



TITLE:

Use of preoperative haemostasis and ABO blood typing tests in children: a retrospective observational study using a nationwide claims database in Japan

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# BMJ Open Use of preoperative haemostasis and ABO blood typing tests in children: a retrospective observational study using a nationwide claims database in Japan

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## ABSTRACT

**Objectives** To describe the prevalence and factors associated with preoperative haemostasis and ABO blood typing tests for children because these tests might represent low-value care.

**Design** A retrospective observational study.

**Setting** Nationwide insurance claims database in Japan.

**Participants** Patients aged 1–17 years who underwent common non-cardiac surgeries between April 2012 and March 2018 were included. Patients with high-risk comorbidities for bleeding (n=175) and those with multiple eligible surgeries were excluded (n=2121).

**Main outcome measures** We described the proportions of each preoperative test performed within 60 days before an index surgery, including platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT) and ABO blood typing tests. We also explored the associations between patient-level and institutional-level factors and any preoperative tests, using multilevel logistic regression analysis.

**Results** We included 13 018 patients (median (IQR) age, 5.2 (2.9–7.7) years; 8276 (63.6%) boys) from 1499 institutions. The overall proportion of each test was as follows: platelet count, 78.6%; PT, 54.4%; aPTT, 56.4% and ABO blood typing tests, 50.4%. The proportion of patients undergoing any preoperative tests in the overall sample was 79.3%. Multilevel logistic regression analysis indicated that preoperative tests were associated with type of anaesthesia (general anaesthesia: adjusted OR 7.06; 95% CI 4.94 to 10.11), type of surgery (tonsillectomy: adjusted OR 3.45; 95% CI 2.75 to 4.33) and surgical setting (inpatient procedure: adjusted OR 5.41; 95% CI 3.83 to 7.66). There was one postoperative transfusion event (0.008%) in the entire cohort and 37 postoperative reoperation events for surgical bleeding after tonsillectomy (0.90%).

**Conclusions** In the largest Japanese cohort reported to date, preoperative haemostasis and ABO blood typing tests were performed in a majority of children prior to common paediatric surgeries. Preoperative tests were associated with anaesthesia, surgical type and surgical setting.

## Strengths and limitations of this study

- This is the first and largest study to investigate the epidemiology of preoperative testing among children undergoing non-cardiac surgery by using the nationwide insurance claims database.
- The study included children who have not typically been investigated in previous studies regarding preoperative testing.
- Baseline information about overuse of preoperative tests in Japan was established.
- Limitations of this study include its retrospective nature and generalisability to other countries with different clinical practices and healthcare systems.
- Detailed information, such as patients' symptoms and results of blood tests, was lacking.

## INTRODUCTION

The inappropriate use of medical service has gained much attention and has led to the Choosing Wisely (CW) initiative, which aimed to reduce unnecessary tests, treatments and procedures.<sup>1</sup> As part of the CW campaign, the American Society of Anesthesiologists recommends this: 'Do not obtain baseline laboratory studies in patients without significant systemic disease undergoing low-risk surgery'.<sup>2</sup> Although the practical guidelines and textbooks consistently describe the inappropriateness of routine preoperative tests,<sup>3–5</sup> they do not cover paediatric patients who will undergo elective procedures or surgeries. There is a paucity of data describing this important cohort of patients. In the guideline from the French Society of Anesthesiology and Intensive Care (SFAR), routine preoperative coagulation and ABO blood type screening tests for elective paediatric surgery were generally not recommended.<sup>6 7</sup> A recent national study conducted in France including 0.24 million children showed that

even the reoperation rates for postoperative bleeding were very low, with a large number of patients undergoing the coagulation (49%) and ABO typing (50%) tests before adenoidectomy and tonsillectomy.<sup>8</sup> This French study suggested an inconsistency between the guidelines and real-world practice.<sup>6–8</sup>

In general, routine preoperative blood tests, without clinical indications, are representative of low-value care and cannot be justified.<sup>5,9</sup> Routine preoperative tests for children do warrant a reconsideration of their clinical utility, as they are costly, time consuming and especially stressful (even painful) for children. Despite its clinical and public health importance, limited information is available regarding the frequency of these preoperative tests before elective paediatric surgery and the manner in which their utilisation is affected by individual patient-level and institutional-level characteristics in a real-world setting. Hence, it is important to establish baseline data to understand the problem of low-value care.<sup>10,11</sup> Therefore, we aimed to estimate the proportion of children who underwent preoperative haemostasis and ABO blood typing tests prior to common paediatric surgery in Japan. Moreover, we sought to identify the patient-level and institutional-level factors associated with preoperative tests.

## MATERIAL AND METHODS

This retrospective observational study was conducted according to the ‘Strengthening the Reporting of Observational Studies in Epidemiology’ guidelines.<sup>12</sup>

### Data sources

The data were provided by a commercial database vendor, JMDC (Tokyo, Japan).<sup>13</sup> The JMDC database is one of the largest commercial claims databases available in Japan, with claims from approximately 18% of all society-managed health insurance associations in Japan.<sup>14</sup> This database has accumulated reimbursement data from 5.6 million insured individuals since 2005. In particular, the JMDC database contains claims data of employees as well as their families, who can access freely to any health-care facility (public and private) under universal health coverage in Japan. The database contains the following information: patient demographic information (age and sex), medical and pharmacy claims data (inpatient, outpatient and emergency department), clinical diagnoses coded using the International Classification of Diseases 10th revision (ICD-10), and medical procedures defined using Japan-specific standardised procedure codes (K codes).<sup>13,15</sup> This database was widely used in epidemiological studies, and details of the database have been previously described.<sup>13,15–17</sup>

### Study population

We used these original Japanese K codes to identify the eligible common paediatric surgeries (otolaryngology, head and neck surgery, including tonsillectomy with or

without adenoidectomy, ophthalmological surgery (strabismus surgery or eyelid surgery for congenital ptosis), superficial surgery (inguinal hernia or umbilical hernia) and urological surgery (surgery of an undescended testis, hypospadias or circumcision); online supplementary table S1) from 1 April 2012 to 31 March 2018. Included surgeries were commonly performed in children and based on the previous literature.<sup>8</sup> We especially chose tonsillectomy as the representative procedure in this study because tonsillectomy is one of the most commonly performed paediatric surgeries, a surgical procedure with relatively high risk of bleeding, and is a well-studied procedure in children.<sup>8</sup> We included patients aged 1–17 years with at least 12 months of insurance eligibility before their index surgery, who had at least one claim during the study period.<sup>15</sup> Patients with high-risk comorbidities for bleeding (ie, patient with coagulopathy including hereditary bleeding disorders or with any malignancy, including leukaemia and lymphoma)<sup>18</sup> who underwent an eligible procedure were also excluded.<sup>8</sup> To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.<sup>16</sup>

## Outcomes

Medical billing within 60 days before the index procedure (but not including the day of the index surgery) was used to identify our primary outcome, according to previous studies,<sup>10,16</sup> which included the receipt of any of the following preoperative blood tests: platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT) and ABO blood typing tests.<sup>8</sup> The Japanese claims codes used in this study are provided in online supplementary table S2.

To explore the clinical significance of these coagulation tests (PT or aPTT) more closely, we performed a supplementary analysis using a subcohort of restricting patients who underwent tonsillectomy with or without adenoidectomy, because their postoperative bleeding is relatively common, compared with other patients undergoing low-risk procedures. We examined the reoperation rate attributed to bleeding 1–14 days after surgeries.<sup>19</sup> We defined the reoperation after tonsillectomy as reoperation for haemostasis due to post-tonsillectomy bleeding (K377 and K367) based on the previous studies.<sup>19,20</sup> In addition, we collected red blood cell transfusions during the first two postoperative days (including the day of index surgery) as postoperative adverse events based on the previous study.<sup>8</sup>

## Predictor variables of preoperative tests

We examined several predictors of preoperative tests, including patient demographics (age and sex), comorbidities, type of anaesthesia, surgical procedure, surgical setting and medical facility status, based on clinical experience and previous literatures.<sup>8,16</sup>

Diagnostic ICD-10 codes within the 360 days before an index surgery, except the month of the index surgery,





**Table 2** Proportions of preoperative haemostasis and ABO blood typing tests in the study cohort

Type of procedure	Tests; % of patients (95% CI)				
	Platelet count	PT	aPTT	ABO	Any tests
Overall (n=13018)	78.6 (77.9 to 79.3)	54.4 (53.5 to 55.2)	56.4 (55.5 to 57.2)	50.4 (49.5 to 51.3)	79.3 (78.7 to 80.0)
Procedure category					
Tonsillectomy procedure (n=4104)	95.5 (94.9 to 96.1)	83.9 (82.7 to 85.0)	85.7 (84.7 to 86.8)	79.3 (78.1 to 80.6)	96.7 (96.1 to 97.2)
Other procedures (n=8914)	70.9 (69.9 to 71.8)	40.8 (39.8 to 41.8)	42.9 (41.8 to 43.9)	37.1 (36.1 to 38.1)	71.4 (70.4 to 72.3)
Anaesthesia category					
Procedure under general anaesthesia (n=10683)	91.0 (90.5 to 91.6)	64.9 (64.0 to 65.9)	67.4 (66.5 to 68.3)	61.0 (60.1 to 61.9)	91.9 (91.4 to 92.4)
Procedure under other anaesthesia (n=2335)	21.8 (20.2 to 23.5)	5.9 (4.9 to 6.8)	5.8 (4.9 to 6.8)	1.8 (1.3 to 2.3)	22.0 (20.3 to 23.7)

aPTT, activated partial thromboplastin time; PT, prothrombin time.

tests, for the entire cohort and for each procedure category (tonsillectomy and other procedures). Continuous variables are presented as median (IQR), whereas categorical variables are presented as number (proportion).

To consider the nesting of all patients within medical institutions, we conducted a multilevel logistic regression analysis. We included all covariates except ‘institution’ as fixed effects; thus, age, sex, comorbidities, type of anaesthesia, surgical procedure, surgical setting, number of beds at the medical facility, teaching hospital status and surgical volume quartile were included based on clinical relevance and previous studies.<sup>10 15 16</sup> The institution was used as a random effect, to account for clustering effects in ordering preoperative tests across medical institutions.<sup>10 16</sup> The adjusted OR and 95% CI were reported, along with the p values. We summarised the interinstitutional variation in the utilisation pattern of preoperative tests between medical institutions in terms of the median OR (MOR), which is the transformation of the random effect variance into an OR scale.<sup>23–25</sup> The MOR indicates heterogeneity in the ordering pattern of preoperative tests by comparing two individuals with the same covariates from two different randomly chosen medical institutions.<sup>16</sup> MOR can be directly compared with the OR of fixed-effect variables.<sup>23 25</sup> The 95% CI for the MOR was calculated from 5000 bootstrap resampled data sets.<sup>24</sup>

Subgroup analyses, as planned priori, were performed according to the type of anaesthesia (general anaesthesia vs other anaesthesia) and the type of surgery (tonsillectomy vs other procedures).

Restricting the subcohort undergoing tonsillectomy procedure, we compared the patients with coagulation tests (PT or aPTT) to those without such tests using the  $\chi^2$  test. Penalised logistic regression analysis (Firth’s penalised likelihood approach)<sup>26</sup> adjusted for patient demographics (age and sex) was used to examine the association between preoperative coagulation tests and post-tonsillectomy bleeding.

All analyses were performed using SAS V.9.4 for Windows (SAS Institute. A two-sided  $\alpha$  level of 0.05 was considered statistically significant.

### Patient and public involvement

This study has no patient or public involvement in the development of its design or implementation.

## RESULTS

### Study cohort

Figure 1 shows the study flow diagram. The initial cohort undergoing eligible surgery consisted of 29830 eligible procedures. The final cohort comprised 13018 patients from 1499 institutions between 1 April 2012 and 31 March 2018 (figure 1).

### Characteristics of the study cohort

Table 1 summarises the patient-level and institutional-level characteristics. Among the patients included, 63.6% were male (n=8276); the overall median (IQR) age was 5.2 (2.9–7.7) years. Moreover, 80.3% (n=10454) and 82.1% (n=10683) of the procedures were performed in an inpatient setting and under general anaesthesia, respectively. Tonsillectomy procedures accounted for 4104 (31.5%) of all the procedures included.

### Prevalence of preoperative tests

Table 2 shows the proportions of preoperative haemostasis and ABO blood typing tests for the entire cohort and for each procedure and anaesthesia category. The proportion of any preoperative test in the overall cohort was 79.3% (95% CI 78.7% to 80.0%). The overall proportion of each test was as follows: platelet count, 78.6% (95% CI 77.9% to 79.3%); PT, 54.4% (95% CI 53.5% to 55.2%); aPTT, 56.4% (95% CI 55.5% to 57.2%) and ABO blood typing tests, 50.4% (95% CI 49.5% to 51.3%). The overall proportions of each test in patients undergoing tonsillectomy (4104 patients) were higher than those undergoing other procedures (platelet count, 95.5%; PT, 83.9%; aPTT, 85.7% and

**Table 3** Multilevel logistic regression analysis of the characteristics associated with any preoperative tests (haemostasis or ABO blood typing tests) for children undergoing common non-cardiac surgeries

Characteristic	Adjusted OR	95% CI	P value
Age, years			<0.001*
1–3	Reference		
4–10	1.24	1.06 to 1.44	0.0059
11–17	1.59	1.28 to 1.97	<0.001
Sex			
Male	Reference		
Female	1.12	0.98 to 1.29	0.10
Comorbidities			
Asthma	1.29	1.12 to 1.48	<0.001
Obesity	1.30	0.28 to 6.05	0.73
Type of anaesthesia			
Not general anaesthesia	Reference		
General anaesthesia	7.06	4.94 to 10.11	<0.001
Type of procedures			
Other procedures	Reference		
Tonsillectomy procedure	3.45	2.75 to 4.33	<0.001
Surgical setting			
Outpatient procedure	Reference		
Inpatient procedure	5.41	3.83 to 7.66	<0.001
No of beds			
<100	Reference		
≥100	1.91	1.41 to 2.57	<0.001
Teaching facility			
Teaching hospital	Reference		
Non-teaching hospital	0.77	0.55 to 1.09	0.14
Procedure volume quartile			0.0018*
Q1 (lowest)	Reference		
Q2	1.18	0.91 to 1.52	0.22
Q3	1.63	1.10 to 2.40	0.015
Q4 (highest)	2.23	1.15 to 4.31	0.018
MOR†	2.89	2.69–3.24‡	

\*Overall p value.

†MOR indicates the interinstitutional variation of the utilisation of preoperative tests.

‡The 95% CI for MOR was calculated by bootstrap resampling method.

MOR, median OR.

ABO blood typing tests, 79.3%). The overall proportions of each test under general anaesthesia were higher than those under other anaesthetic methods.

## Multilevel logistic regression analyses

Table 3 shows the adjusted OR of the patient-level and institutional-level factors with any preoperative tests. Patient medical factors (older age or asthma) were associated with the preoperative tests, but their adjusted ORs were relatively weak. There were significant associations between any preoperative tests and the type of anaesthesia (general anaesthesia: adjusted OR 7.06; 95% CI 4.94 to 10.11) relative to the reference group of other anaesthesia, type of surgery (tonsillectomy: adjusted OR 3.45; 95% CI 2.75 to 4.33) relative to the reference group of the other procedures, and surgical setting (inpatient surgery: adjusted OR 5.41; 95% CI 3.83 to 7.66). The MOR for interinstitutional variation was 2.89 (95% CI 2.69 to 3.24).

## Postoperative adverse events

The incidence of postoperative transfusion events within postoperative 2 days was one patient (0.008%; one patient underwent hernia surgery) in the whole cohort. The incidence of postoperative reoperation for surgical bleeding after tonsillectomy was 0.90% (37 of 4104); 31 of 3527 (0.88%) in patients undergoing preoperative coagulation tests and 6 of 577 (1.04%) in patients without preoperative tests (unadjusted OR 0.84; 95% CI 0.35 to 2.03,  $p=0.70$ ). Penalised logistic regression analysis revealed that the adjusted OR of preoperative coagulation tests for postoperative re-operation was 0.74 (95% CI 0.34 to 1.91,  $p=0.60$ ).

## DISCUSSION

We found that the preoperative tests were performed in a majority of children before undergoing common non-cardiac surgeries. Preoperative testing was strongly associated with type of anaesthesia, type of surgery and surgical setting. There were quite low postoperative transfusion events, and no statistically significant difference in postoperative reoperation for surgical bleeding was found between patients with or without preoperative coagulation tests.

As the increased overuse globally, problems of low-value care have gained more attention recently.<sup>9</sup> To our knowledge, our study is the largest and most comprehensive population-based study investigating the preoperative tests before common paediatric surgeries. Our database could capture the whole series of preoperative tests ordered both at inpatient and outpatient settings. Therefore, our analysis can precisely describe the current preoperative testing status in Japan. Previous French nationwide cohort study did not have medical services data, including tests or procedures during inpatient episodes.<sup>8</sup> This recent French study showed that coagulation and ABO blood typing tests were performed in 49% and 50% of children before tonsillectomy, respectively.<sup>8</sup> Although the SFAR guideline did not recommend preoperative tests among children undergoing elective tonsillectomy,<sup>6,7</sup> there was still a high rate of unnecessary preoperative tests on paediatric patients.<sup>8</sup> Our results

demonstrated that most children undergoing tonsillectomy underwent coagulation (PT, 84% and aPTT, 86%) and ABO blood typing (79%) tests, which were markedly higher compared with those of the recent French study.<sup>8</sup> Although not all of these preoperative tests are clinically inappropriate, preoperative coagulation tests for screening or predicting coagulopathy risk were not recommended. Standard haemostatic assessments (PT, aPTT and platelet count) cannot help in detecting the most common congenital bleeding disorders, such as von Willebrand disease or haemophilia A, and cannot help in predicting perioperative bleeding risk. The predictive value of haemostatic tests (PT, aPTT and platelet count) for determining perioperative bleeding risk of children undergoing tonsillectomy is generally poor, with a low sensitivity of <44% and a positive predictive value of <29%.<sup>7</sup> In walking-age children, a standardised questionnaire (personal or family history of haemorrhagic diathesis) and physical examination are more sensitive than laboratory tests in the detection of bleeding risk.<sup>7 27</sup> Abnormal results were not always associated with hereditary blood disease.<sup>7 8</sup> False positive results can trigger further tests, leading to inappropriate perioperative management and delay or cancellation of elective surgeries.<sup>5 8</sup> The increasing number of blood tests can burden children and parents. As children consider phlebotomy as one of the most frightening and painful health-related events, frequent experiences can lead to increased distress in future procedures and development of needle fears, potentially leading to healthcare avoidance behaviours.<sup>28</sup>

Regarding the association of preoperative tests, we found a markedly high adjusted OR for the type of anaesthesia and surgical setting. There was also a relatively high MOR for medical institutions (ie, the odds of receiving preoperative tests between two randomly selected medical institutions varied by 2.89 times), suggesting interinstitutional variation in ordering preoperative tests in children. These results were consistent with our previous report on low-risk surgeries in Japan showing that preoperative blood tests performed in adult patients before undergoing low-risk surgery (eg, cataract, superficial surgery) were strongly associated with the type of anaesthesia, patient characteristics and medical facility status.<sup>15-17</sup> Especially, the type of anaesthesia was the most important predictors in our study focused in children and previous adult studies.<sup>16</sup> However, our findings were in opposition to the SFAR guidelines, which recommended that haemostasis tests should not be ordered regardless of anaesthesia type.<sup>7</sup> A guideline for preoperative tests has not been established in Japan, and there is little consensus on whether preoperative testing is required, leading to variations in ordering patterns. Moreover, certain hospital factors, including policies for preoperative management, provider preference or the defensive medicine, may partially explain this overuse and interinstitutional variation.<sup>15 16</sup>

Our supplementary analysis showed that the need for postoperative transfusion within 2 days was very rare.

Moreover, reoperation incidence for post-tonsillectomy bleeding (objective and reliable end point for evaluating clinically relevant bleeding after tonsillectomy)<sup>19 20</sup> was low (0.9%), consistent with previous reports,<sup>19 20</sup> and there was no statistically significant difference between patients with or without preoperative coagulation tests. A previous randomised trial demonstrated that perioperative outcomes after low-risk surgery were not different in patients with or without preoperative tests.<sup>29</sup> Previous studies have investigated the utility of haemostasis tests in predicting bleeding risk among children undergoing tonsillectomy, and a majority of studies concluded that the predictive value of preoperative haemostasis tests was poor.<sup>7</sup> The preoperative coagulation tests before paediatric non-cardiac surgery are largely unnecessary. It is important to reduce these tests unless there is a clear indication not only because of the low-value care, which provides little or no benefit at all, but also increasing cost of related healthcare. In 2016, the Japanese government estimated that at least 2.4 million general anaesthesia cases were performed annually, with patients aged 5 years and younger accounting for 2.7% of total inpatient procedures performed under general anaesthesia (approximately 65 000 cases).<sup>30 31</sup> It is apparent that increasing preoperative test overuse will burden the Japanese healthcare system in future. Our findings could provide valuable baseline data about preoperative testing overuse for not only clinicians but also for policy-makers and promote the need for reconsidering the routine clinical practice and the cost of these tests.<sup>8 15</sup>

This study has several limitations. First, our claims database lacked important clinical information, such as patients' and family history of bleeding, symptoms or abnormal physical examination, which may have influenced the indication of preoperative tests. As we did obtain neither the patient's nor the family's history of bleeding, we excluded the patients with diagnostic codes indicating hereditary bleeding disorders. The exclusion of patients with high-risk comorbidities for bleeding was based on ICD-10 codes using components of the Elixhauser Comorbidities Index.<sup>18</sup> Although the Elixhauser Comorbidities Index is a validated measure of comorbidities in insurance claims databases, similarly to that used in this study,<sup>32</sup> the diagnostic accuracy of each component was not validated in Japan. Thus, misclassification of comorbidities can lead to underestimation. Second, how the abnormal results of preoperative tests have affected perioperative course was unknown. As our database did not have the results of the blood tests, we were not able to interpret whether the coagulation test results were normal or abnormal. Therefore, we did not analyse the sequela of these findings. Third, there may be a selection bias with the inclusion of only specific paediatric surgeries in this study. However, we carefully chose to include common paediatric surgeries based on the recent publications.<sup>8 19</sup> We used tonsillectomy procedures as a representative scenario to compare our study with previous investigations.<sup>8</sup> Fourth, we could not access the data from



the physician who ordered the preoperative tests and could not investigate the effects of clinician-related practice pattern. A previous study of low-risk surgery revealed that the practice patterns of the physicians were more likely associated with the preoperative testing rather than patients' comorbidities.<sup>22</sup> In the future exploration, it is necessary to determine whether the degree of variation is rooted at the institutional or individual provider levels.<sup>33</sup> Given that our MOR for interinstitutional variation was 2.89, it would be important to compare institutions with high and low orders for these tests to investigate the reasons for their practice variation. Finally, this nationwide study limits the results' generalisability to other countries with different clinical practices and healthcare systems.<sup>15 16</sup> Nevertheless, our study can add significantly to the growing evidence on the prevalence of medical overuse worldwide.

## CONCLUSION

Preoperative haemostasis and ABO blood typing tests were performed in a majority of children before undergoing common paediatric surgeries despite the low postoperative transfusion and reoperation events. Preoperative tests were associated with the anaesthesia, surgical type and surgical setting.

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**Contributors** HY conceived the study, collected, analysed, interpreted the data and results, and drafted the manuscript. KI analysed the data and performed statistical analyses. HY, KI, YK, CT, YN, YM, MS, KK and MK conceived the study and interpreted the data and drafted the manuscript. All authors critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

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**Competing interests** KK received honoraria from Shin Nippon Biomedical Laboratories; research funds from Bayer Yakuhin, CMIC, Novartis Pharma K.K., Suntory Beverage & Food, Daiinippon Sumitomo Pharma and Stella Pharma; and holds stocks in School Health Record Center and Real World Data. There are no patent products under development or marketed products to declare, relevant to those companies.

**Patient consent for publication** Not required.

**Ethics approval** This study was by the Ethics Committee of Mie University Graduate School and Faculty of Medicine (approval number: H2018-094), who waived the requirement for obtaining informed consent from the patients due to the anonymous nature of the data.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request.

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**Author note** This retrospective observational study was conducted according to the 'Strengthening the Reporting of Observational studies in Epidemiology' (STROBE) guidelines.

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